Personal Care Products Council
Committed to Safety, Quality & Innovation

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BY FIRST-CLASS MAIL AND E-MAIL

John R. Williams Jr.
Department of Ecology
PO Box 47600
Olympia, WA 98504-7600
jowi461@ecy.wa.gov

Dear Mr. Williams:

The Personal Care Products Council (Council)[1] is pleased to submit the following comments on the "Draft CSPA Reporting Rule" (Draft Rule) dated July 28, 2010, which is being promulgated by the Washington Department of Ecology (DOE) in consultation with the Department of Health to implement the Children's Safe Product Act of 2008 (CSPA).

INTRODUCTION

The Draft Rule addresses a number of important items, including the list of priority chemicals of high concern for children (CHCC), notice requirements for manufacturers of those priority chemicals, and how the notice requirements will be enforced. The Council will address these items in turn, as well as highlight some additional concerns for you to consider as DOE moves toward the formal proposed rulemaking.

Of particular concern for the Council are two items: (1) the listing of parabens on the CHCC list; and (2) the lack of a feasible *de minimis* level for chemical reporting.

With respect to parabens, it is not clear what criteria the DOE utilized for adding them to the CHCC list. The Council previously provided DOE with detailed analyses as to why parabens should be excluded from the proposed CHCC list, yet there appears to have been little consideration of this input – or at

[1] Based in Washington, D.C., the Council is the leading national trade association representing the $250 billion global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on everyday, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation. The Council was previously known as the Cosmetic, Toiletry, and Fragrance Association (CTFA).

least no explanation as to why the input was disregarded and parabens ultimately listed. As such, the Council respectfully requests that DOE extrapolate upon its reasons for listing parabens on the CHCC list.

Likewise, the Council believes that the proposed 10 ppm reporting threshold essentially equates to a detection-level threshold when you consider that 10 ppm is within typical variation for testing for the presence of a chemical. A more reasonable threshold would be 0.1% by weight, which is a generally accepted *de minimis* value in similar chemical management frameworks (e.g., European Union's R.E.A.C.H. legislation).

These concerns, along with additional considerations, are addressed further below.

CHEMICAL LISTING PROCESS

The Council has some concerns about the chemical selection and prioritization process employed by DOE in this Draft Rule. Consider, for example, that the CSPA correctly set a high bar for listing CHCC by requiring that it be done on the basis of credible scientific evidence where chemicals are "known" to have certain toxicological endpoints or impacts. Yet DOE draws from sources that list chemicals as "presumed" or "suspected" of having a specific endpoint or causing harm when identifying CHCC. Similarly, there doesn't appear to be any consideration of "severity" of hazards. Shouldn't chemicals with multiple hazards traits or routes of exposure be a higher priority?

As DOE focuses its resources on identifying and prioritizing chemicals and exposures with the greatest potential to impact human health, it should establish clear criteria on how it will identify, prioritize, assess, and manage CHCC. This will also provide additional transparency for the regulated community.

Endocrine Disruptors

The Council strongly opposes DOE listing "endocrine disrupting" chemicals as high priority and recommends removing them before issuing the proposed rule. Endocrine disruption is a mode of action, not a toxicological endpoint. Simply because a chemical is speculated to have the potential to interact with the endocrine system does not mean it constitutes a risk, much less will result in an adverse health effect. Before listing a chemical, there should be a scientifically credible and proven link between a chemical's interaction with the endocrine system and an adverse health effect, something DOE has not demonstrated with the current list.

The European Union's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) – the official science advisory panel to the European Commission – echoed the concerns about confusing endocrine disruption as toxicological endpoint:

> "It is important to realize that endocrine disruption is not a toxicological endpoint *per se* as is cancer or allergy, but that it is a descriptor for a functional change that may lead to adverse

health effects. Rather, endocrine disruption should be seen in the context of well-established endpoints, primarily reproductive toxicity and impaired development." [2]

Moreover, basic toxicological tests (e.g., reproductive, developmental, sub-chronic toxicity) already measure endpoints that would capture adverse health effects brought on by interaction with the endocrine system, making the listing of endocrine disrupting chemicals unnecessary.

Despite this, CSPA included chemicals suspected of causing disruption of the endocrine system as one of the criteria for chemical selection, and the Draft Rule contains 13 chemicals that are listed solely because of their endocrine disrupting potential. The Council strongly recommends removing these 13 chemicals from the Draft list of chemicals until more reliable assessment techniques or consensus conclusions are available for evaluating endocrine disruption potential and its relationship to health outcomes.

DOE apparently relied on the European Commission's 1999 Report (EU Report)[3] concerning endocrine disrupting chemicals for listing the 13 chemicals as CHCC. Such reliance is misplaced, however, especially when you consider that CSTEE did "not find the source material, methodology and selection criteria used to be scientifically adequate" and concluded "that there are important shortcomings" with the EU Report. Coupled with the fact that the EU Report lacked any deliberative scientific review by appropriate EU authorities, public input, or scientific consensus, it is easy to see why the EU Report is not a reliable source and should not be used as the basis for any chemical listing decisions.

SPECIFIC CHEMICALS

Parabens

The Council strongly opposes the listing of methyl, ethyl, propyl, and butyl parabens on DOE's chemicals of high priority list.

Parabens function as preservatives and are highly effective in preventing the growth of microorganisms such as bacteria and fungi and are used to greatly extend product shelf life. These FDA-approved ingredients have been used for decades in the food, drug and cosmetic industries. They are effective at low use levels, possess a broad spectrum of antimicrobial activity, are relatively non-irritating, non-sensitizing, and of low toxicity, are stable over a wide pH range, and are sufficiently water soluble to be

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[2] EU CSTEE, Opinion on BKH Consulting Engineers Report; accessible at: http://ec.europa.eu/health/ph_risk/committees/sct/docshtml/sct_out73_en.print.htm).

[3] European Commission (1999): Communication from the European Commission to the Council and the European Parliament on the implementation of the Community strategy for endocrine disrupters. COM (99)706.

effective in the aqueous phase of formulations. These characteristics make them especially versatile and valuable as preservatives.

Parabens are currently reported to FDA under its Voluntary Cosmetic Registration Program, and they are widely used across many product categories. In addition, two of the parabens (methyl and propyl) have been classified by FDA as "GRAS" (Generally Recognized As Safe) for direct addition to food as preservatives at use limits of 0.1% each. Moreover, parabens, like other cosmetic ingredients, are listed on the finished product label. Reporting their use to DOE would be redundant.

Under a weight-of-evidence analysis it is easy to conclude that parabens are safe. In fact, the only hazard information that would support their listing is contained in the EU Report (discussed above), which has been since discredited and therefore should not be utilized in selecting CHCC for reporting.

Diethyl Phthalate

Diethyl phthalate has been extensively tested for reproductive and developmental effects, and results have been consistently negative. Diethyl phthalate has been approved for its use in cosmetics by both the Cosmetic Ingredient Review in the United States and by the Scientific Committee on Consumer Products in Europe.

As with parabens, DOE relied on the EU Report in listing diethyl phthalate as a CHCC. For the reasons cited above, the Council recommends removing this chemical from the Draft list.

ADDITIONAL CONSIDERATIONS

Listing and Delisting Petitions:

Petitions for listing or delisting a chemical from the CHCC list should adhere to a verifiable weight-of-evidence analysis to be submitted before DOE reviews a petition. The "weight-of-evidence" approach generally means a transparent, criteria-based, methodological evaluation to review and interpret all available and relevant scientific research for a given chemical. This would also provide a specific process against which DOE could objectively assess a chemical for inclusion or delisting.

To that end, the Council recommends that DOE include in its proposed rule details on the following:

- Specific requirements needed in a petition to add or delist a chemical. In particular, DOE should make clear the scientific standard for adding a chemical to the list; and it should clarify what it means by "credible scientific information" when judging whether to delist a chemical.

- Details on the process DOE will utilize to ensure that all appropriate relevant data are considered before making a decision.

Detection vs. Exposure:

CSPA states that manufacturers must notify DOE when a listed chemical is "present" in one of its products. Setting the detection baseline reporting trigger at 10ppm as the trigger for reporting is too onerous and the reason for setting the trigger at this level is unclear. There is no corresponding public health protection basis for such a threshold, and in fact, most authoritative bodies recognize a threshold reporting level of 0.1% by weight. The 0.1% level is sufficiently protective of public health, and would harmonize with both domestic and international jurisdictions, easing the compliance burden on the regulated community. As such, the Council recommends that DOE adopt 0.1% by weight as the trigger level for reporting under the rule.

The Council would also recommend that DOE exclude chemicals exceeding the trigger level that are not intentionally-added, or are contained in components that are inaccessible, from reporting.

Intentionally Added:

CSPA seems to imply that its application is to intentionally added chemicals only, since it calls for chemical information such as CAS number, description of the chemicals function in the product, the amount used, etc., which means only intentionally added chemicals should be covered by the reporting requirements. For this reason, the Council recommends that the scope of the rule be limited to "intentionally added" product ingredients that serve a functional purpose.

Reporting:

The Council strongly supports the draft language allowing a trade organization to report on behalf of companies, helping to ease the burden of compliance. Also, if reporting is to be phased-in, it should be based on the hazard of the chemical, intended exposure route and likelihood of exposure, which would appropriately put the focus on product safety and human health.

Products Covered:

One of the difficulties in assessing the impact of this proposed regulation is due in part to the uncertainty about which products this regulation will apply to. While the council recognizes that the underlying statute defines "children's products," the actual scope of this implementing regulation still remains unclear. The Council recommends clarifying the scope of this regulation by identifying, even generally, which products and product categories will be impacted and the process for making that determination.

Confidential Business Information:

The Council supports the language in the Draft Rule that provides for the protection of Confidential Business information. To that end, the Council encourages DOE to develop specific protocols regarding how it will determine what constitutes CBI so that companies/associations can be certain that trade secret information is adequately protected.

CONCLUSION

The Council gratefully acknowledges DOE's willingness to engage stakeholders in a thoughtful dialogue about the merits and deficiencies of its Draft Rule before moving forward with proposed regulations, and we look forward to continuing this discussion.

To the extent the Council can be of any assistance to you on this or any other issue, please let us know.

Respectfully submitted,

Thomas F. Myers
Associate General Counsel